REMARKS

It is respectfully requested that this application be reconsidered in view of the above amendments and the following remarks and that all of the claims remaining in this application be allowed.

Interview

The undersigned notes with appreciation the courtesies extended by Examiners Ulm and Chernyshev to both himself and Mr. Bill Chan (assignee's representative) during the personal interview conducted for this application on May 26, 2005. The Summary of the Interview accurately reflects the discussions held some of which are elaborated upon below.

For discussion below, the following points were discussed and addressed during the interview and specifically addressed in the Summary of the Interview:

1. Based on Applicants proposed claim amendments and arguments that the claims in this application were directed to composition claims and not method claims, the rejection under 35 U.S.C. §112, first paragraph, would be withdrawn;

2. Because Applicant is presenting composition claims, the rejection under 35 U.S.C. §102(b) over Bombeli, et al., Blood, 89(7):2429-2442 (1997) would be reinstated against Claim 16 and claims dependent therefrom.

3. Claims directed to a unit dosage (Claims 19, 47-48 and 53) appear to be free of the prior art.

In order to expedite prosecution of this application, Applicants will address the above points in this response.

Amendments

Claims 1-15 were previously canceled.

Claims 16 was amended to recite that the pharmaceutical composition is for administration to a human patient. Support for this amendment is found in Applicants' specification at, for example, page 5, lines 1-7.

Claim 16 was amended to delete the objected to phrase "an effective amount".

Claim 16 was amended to recite a human cellular composition comprising apoptotic bodies and/or apoptotic cells and optionally necrotic bodies and/or necrotic cells. Support for this amendment is found in Applicants' specification at, for example, page 7, lines 10-18, as well as at page 10, lines 25-28. Further support for the optional presence of necrotic bodies and/or necrotic cells is found, for example, at page 9, lines 16 et seq.

Claim 16 was further amended to recite that the cellular composition is suitable for administration to the patient. Support for this recitation is found in Applicants' specification at, for example, page 11, lines 12-22.

Claims 16 and 19 were amended to add the language, "wherein said apoptotic bodies and/or apoptotic cells exhibit at least two characteristics comprising DNA fragmentation, surface exposure of phosphatidylserine, or altered mitochondrial membrane permeability,". This amendment was entered solely to clarify the biological properties of the apoptotic bodies and /or apoptotic cells used in the claimed methods. Support for these amendments can be found, for example, at page 2, line 2 – page 4, line 12 and page 6 line 22 – page 7, line 9 of the specification.

Claim 17 was amended to recite a human cellular composition comprising apoptotic bodies and/or apoptotic cells and necrotic bodies and/or necrotic cells wherein said necrotic cells and/or bodies comprise no more than 10 weight percent of the cellular composition. Support for this amendment is found in Applicants' specification at, for example, page 7, lines 10-18, as well as at page 10, lines 25-28.

Claim 18 was amended to recite that the apoptotic bodies and/or cells are derived from the patient's own body. Support for this amendment is found in Applicants' specification at, for example, page 7, lines 20 *et seq.*

Claims 33-46 have been canceled, without prejudice or disclaimer, as these claims have been deemed to correspond to non-elected Group I (Office Action of December 23, 2004, at page 2). Applicants reserve the right to file a divisional application directed to the subject matter of these canceled claims.

Claim 49 was amended to be consistent with amended Claim 16 and to employ proper claim language.

Claims 53 and 54 are newly added. Claim 53 is similar to amended claim 16 and claim 54 is associated with amended claim 19; however, the new claims recite additional characteristics of apoptotic cells, and/or apoptotic bodies which may be associated with the cells, used to practice the invention. Support for these additional characteristics can also be found, for example, at the above-references pages of the specification.

Claim 55 is also newly added. Claim 55 recites that that the apoptotic bodies and/or cells are derived from an established cell line. Support for this amendment is found in Applicants' specification at, for example, page 7, lines 20 *et seq.*

No new matter has been added. Entry of the above amendments is earnestly solicited.

This amendment adds and deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, Claims 16-17, 19 and 47-55 are now pending in this application.

Rejections of Claims 16-19 and 47-52 under 35 U.S.C. § 112, first paragraph

Claims 16-19 and 47-52 stand rejected under 35 U.S.C. §112, first paragraph as allegedly not satisfying the enablement requirement. This rejection is predicated on the argument that "the claimed invention is directed to means of "*treatment* and or *prophylaxis* of neurodegenerative disorders by the administration of apoptotic cells and/or bodies." Page 3, paragraph 7, of the Office Action (emphasis added).

This rejection is traversed. The claims at issue in the application are *composition* claims, not *method* claims, as suggested by the language from the Office Action. Composition claims 16-19 are drawn to pharmaceutical composition comprising apoptotic cells and/or apoptotic bodies having a defined maximal amount of nercrotic cells which can be optionally present. The preparation of apoptotic cells and/or apoptotic bodies is described in detail in the specification, *e.g.*, at page 7, line 10 – page 10, line 22. Composition claims 47-52 are directed to unit dosages of the compositions of claim 19. Unit dosages are defined by the Applicants in the specification, *e.g.*, at page 10, line 22 – page 11, line 5. Importantly, none of claims 16-19 nor 47-52 recite diseases, treatment, prophylaxis, or any of the terms or phrases against which the enablement issues appear to have been raised.

The arguments set forth in the Office Action from page 3 (bottom) to page 6 (top) appear to discuss enablement issues relating to *methods for treating* neurodegenerative and other neurological disorders. Thus, the Patent Office appears to be implying *method of treatment* limitations from the specification into the pending *composition* claims, then rejecting the claims based on alleged lack of enablement rejection for the implied claim limitations. Consistent with this apparent line of reasoning, the Office Action cites *Genetech, Inc. v. Novo Nordisk*, 42 USPQ2d 1001 (CAFC, 1997), a case which relates to a to *method* claim drawn to the production of a polypeptide[1].

[1] A method of producing a protein consisting essentially of amino acids 1-191 of human growth hormone.

However, rejection of the pending claims based on this line of reasoning is inconsistent with the Patent Office's own guidelines. For example, according to the M.P.E.P. at 2164.01(c):

> When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (claiming a chimeric gene capable of being expressed in any cyanobacterium and thus defining the claimed gene by its use).
>
> In contrast, when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use. If multiple uses for claimed compounds or compositions are disclosed in the application, then an enablement rejection must include an explanation, sufficiently supported by the evidence, why the specification fails to enable each disclosed use. In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention. [Emphasis added].

Here, the pending claims do not recite limitations relating to a particular use. Therefore, according the guidelines established by the Patent Office, if the claims at issue are enabled for any use, the enablement requirement is satisfied.

Based on the Office Action, the Patent Office apparently would not dispute that the claims would be enabled for a use such as treating contact hypersensitivity in mice[2]. Therefore, the claims are enabled for at least one use and the enablement requirement is satisfied for the full scope of the claimed subject matter.

For at least these reasons, Applicants request withdrawal of the outstanding enablement rejection. However, in the interest of expediting prosecution, independent claim 16 has been amended to delete the phrase "effective amount," which presumably eliminates any reason to read treatment limitations from the specification into the composition language of the now pending claims.

As noted above in the Summary of the Interview, Examiners Ulm and Chernyshev, Ph.D., both agreed that this rejection would be withdrawn.

Rejections of claims 16-18 under 35 U.S.C. § 112, second paragraph

Claim 16 stands rejected as allegedly being indefinite for the recitation of "effective amount" without stating an objective. The phrase "effective amount" has been deleted from claim 16, which presumably obviates the rejection.

Withdrawal of this rejection is requested.

Claim 17 was rejected for allegedly lacking antecedent basis for the phrase "necrotic cells." Applicants submit that the amendments to Claim 16 render this rejection moot.

Withdrawal of this rejection is requested.

Claim 18 stands rejected because there is allegedly no antecedent basis in Claim 16 for "liquid suspension of cellular material." Applicants note that Claim 18 has been amended to delete this objected to language. Withdrawal of this rejection is earnestly solicited.

Reinstated Rejection of Claims 16, 17 and 49-52 under 35 U.S.C. §102(b)

In the Summary of the Interview, the Office indicated that it would reinstate the rejection of Claims 16, 17 and 49-52 under 35 U.S.C. §102(b) over Bombeli, et al., Blood, 89(7):2429-2442 (1997) ("Bombeli"). In order to expedite prosecution of this application, Applicants will now address this rejection.

First, for the sake of completion, Applicants wish to note that treated human umbilical vein endothelial (HUVEC) cells disclosed by Bombeli are described at page 2430 as being washed twice with phosphate buffer saline, pH 7.4. Accordingly, all arguments heretofore made

[2] Note that Applicants are in no way conceding that the invention is limited to this use. Applicants are merely identifying at least one use that does not appear to be in dispute.

with regard to Bombeli are now withdrawn and the following new arguments are relied upon instead.

To establish anticipation of a claim, a single prior art reference must teach, either expressly or inherently, each and every element of the claimed invention. See, for example, MPEP §2131; *Verdegaal Bros. v. Union Oil Co. of California*, 814 F2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

In the present case, amended Claim 16 recites a human cellular composition comprising apoptotic bodies and/or apoptotic cells and optionally necrotic bodies and/or necrotic cells. This composition is qualified as is suitable for administration to a human patient.

Amended Claim 17 further defines this amount of necrotic cells and/or bodies as comprising less than 10 weight percent of the cellular composition.

Amended Claim 18 recites that the apoptotic bodies and/or cells are derived from the patient's own body.

In contrast, Bombeli recites none of these recitations. For example, Bombeli recites that his apoptotic HUVEC cells and/or bodies exhibit procoagulant properties and, accordingly, it is submitted that such apoptotic cells and/or bodies are not suitable for administration to a human patient.

As to the Claim 17, Bombeli in his Results section of the article recites that the level of apoptosis induced, as measured by the A_0 region of the DNA fragments was about 75%. There was no indication as to what the other 25% was including whether it contained no more than 10 weight percent necrotic cells.

Bombeli further elaborates upon the level of apoptotic cells in the treated HUVEC cells by measuring the fluorescence (indicative of phosphatidyl serine exposure on the outer leaflet). See, for example, page 2432, left column, last paragraph. Bombeli recites that about 90% of the

cells displayed an enhanced fluorescence due to annexin V binding. Furthermore, to exclude annexin V binding due to necrosis, Bombeli recites a specific protocol and determines that less than 15% of the cells were positive for both PI and annexin V. Applicants submit that this data indicates that of the 90% of the cells displaying enhanced fluorescence, about 15% of these cells were necrotic (or about 16.7% of the total apoptotic/necrotic cells were necrotic).

Such a disclosure fails to teach the recitation of no more than 10 weight percent necrotic cells in Claim 17.

Claim 18 recites that the apoptotic bodies and/or cells are derived from the patient's own body. Contrarily, Bombeli merely discloses HUVEC for use in *in vitro* testing. Such a disclosure fails to teach the recitation of Claim 18.

Absent such a disclosure, any rejection under 35 U.S.C. §102(b) over Bombeli is in error.

CONCLUSION

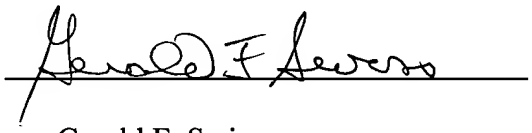
Applicants believe that the present application is in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date 6-23-05

By 

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